TRAUMA DATA EXTERNAL VALIDATION SERVICE

INTRODUCTION:
The process of developing, implementing, and refining a registry data validation system is integral to optimal trauma registry operations. Standardizing the evaluation method of data collection becomes the foundation for analyzing the overall accuracy of registry data. Incorporation of a validation tool and evaluation method is integral for orientation, development, training, benchmarking, and accurate reporting. An objective assessment of data can be achieved through the use of standardized definitions and descriptors, precise measurements, comparative re-abstractions, and structured evaluation.

PURPOSE:
Internal (peer review) and external (independent) data verification/validation processes provide dual complementary structured evaluation methods for registry integrity. Verifying data is often conducted *internally* to evaluate whether the data complies with dictionary definitions, open field options, and parameters for diagnoses, comorbidities, and value-assigned data points. Data validation is performed to ensure data integrity and reliability.

An external validation process is intended to check for accuracy of entered data. Trauma Registry Programs conduct effective internal data validations often utilizing a peer-review model. The goal of the external data validation is to determine if the trauma registry data is entered correctly and in accordance with regulatory definitions and requirements (see References Used for Validation). The COTS provides a data External Validation Service for members to determine if the data reflects the inpatient medical record and has been interpreted according to the State of Ohio Trauma Registry definitions and specifications. This service should be used to support or affirm the results of internal/peer data validation.

- A Primary External Validation Audit will be offered annually to each trauma center in the COTS region.
- A Secondary External Validation Audit is performed every quarter on data download to the COTS Data Base.

The charge for these services is included in your COTS membership fee.

DATA VALIDATION PROCESSES:
Primary External Validation Audit: COTS will offer a Primary External Validation Audit to the Trauma Program Managers annually. The audit will be performed by COTS employees (validators) who have no affiliations with any hospital or health care system. The Trauma Center may request completion of a Conflict of Interest by COTS.

The Trauma Center must secure all administrative and compliance approval for the COTS validators to conduct the audit. The Trauma Program will ensure compliance with all internal processes and Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations.

The *Primary External Validation Audit* is intended to determine if the trauma registry data is entered correctly and in accordance with regulatory definitions and requirements (see References Used for Validation). A trauma program manager may also request a focused audit or that a greater percentage of records be audited. The audit inclusion dates will be determined by the most recent data download to COTS.

- Every trauma center who participates will complete a standard validation study on 3-7% of the population randomly selected by the COTS Regional Data Systems Coordinator.

- A second external validation (focused) study on a subset of patients may be completed if requested by the trauma center. This may include the more difficult and complex records. These records tend to reflect longer length of hospital stay (LOS), higher injury severity scores (ISS) > 15 and complex procedures (Intensive Care Unit {ICU} admission and/or > 2 Operating Room {OR} procedures). The trauma center will notify COTS one-month prior their scheduled date, if a more detailed audit is requested.

- The validation study may be done in person or on-line depending upon the request and requirements of the trauma center.

A *Secondary External Validation* method includes a submission report of data downloads to the COTS Data Repository. Trauma data that is submitted quarterly to COTS will be reviewed for records loading, staging errors, and warning levels. The most current ESO Digital Innovation (DI) submission report becomes immediately available following data download to COTS. The user is notified by automated email.

Error check rates are reviewed by the COTS Regional Data Systems Coordinator. Records producing a level 3 or 4 alert are considered advisory notices. Records triggering a level 1 or 2 alert must be corrected and cannot be submitted to the State of Ohio Trauma Registry. The submission reports may be used to identify performance/process improvement (PI) opportunities.

REFERENCES USED FOR VALIDATION:
References used for data validation include the State of Ohio Trauma Data dictionary, the COTS Trauma Registry, the Abbreviated Injury Severity (AIS) coding rules, and defined Trauma Registry Inclusion Criteria (American College of Surgeons).

SCHEDULING:
The Trauma Program Manager and COTS Regional Data Systems Coordinator will collaboratively schedule the Primary External Validation Audit with the Trauma Program staff. The length of time needed to complete the audit is dependent upon the number of chart to be audited. Data audits may be expected to be completed in two to five days.

CHART SELECTION:

Random chart audit may be completed, if requested by the Trauma Program Manager (TPM). The type and number of cases to be pulled will be negotiated with the COTS staff upon request.

Focus study audit may be chosen from the below categories, as requested by the TPM. The number of cases to be reviewed will be negotiated with the COTS staff upon request.

	Patients Admitted for Trauma Care to the Institution		
	Adults Only	**Adults & Children**	**Children Only**
Neurosurgical injuries			
Epidural/subdural hematoma taken to the operating room	X	X	X
Severe TBI (GCS ≤ 8) admitted to an ICU, excluding the mechanism of Physical Child Abuse	X	X	X
Spinal cord injury with neurologic deficit	X	X	X
Orthopaedic injuries			
Supracondylar elbow fractures with neurovascular compromise		X	X
Any amputations excluding digits	X	X	X
Acetabular fractures and any pelvic fractures requiring embolization, transfusion or surgery/ORIF	X	X	X
Open femur or tibia fractures	X	X	x
Abdominal & Thoracic injuries			
Thoracic/cardiac injuries (include aortic), AIS ≥ 3 or requiring intervention (intubation, surgery, IR)	X	X	X
Solid organ injuries: spleen, liver, kidney, and pancreas: ≥ Grade III or requiring intervention (transfusion, embolization, surgery)	X	X	X
Penetrating neck, torso, proximal extremity trauma, with ISS ≥ 9, or requiring intervention (transfusion, chest tube, IR, surgery)	X	X	X
Non-Surgical Admissions & Transfers			
Physical child abuse (suspected and/or confirmed) with an ISS ≥ 9		X	X
Patients admitted to non-surgical services with an ISS ≥ 9 for nonphysical child abuse	X	X	
Patients admitted to non-surgical services with an ISS ≥ 9 for geriatric hip fractures		X	
Transfer out for the management of acute injury	X	X	X
Adverse Events			
Any major complication, or unexpected return to the SICU/PICU or the operating room	X	X	X
ISS > 25 with survival, without severe TBI (Head AIS < 3)	X	X	X
Massive Transfusion Protocol (MTP)			
This will include: MTP Activation criteria, timing of hemorrhage control, prehospital interventions and timing, resources in the ED, time in the ED with hypotension prior to hemorrhage control, outcomes and timing of consults	X	X	X
Hospice			
Care provided up to the time of transfer will be evaluated	X	X	
Deaths			
Mortality without opportunity for improvement Mortality with opportunity for improvement Unanticipated death with opportunity for improvement	X	X	X

<u>DATA AUDIT OPTIONS</u>:

Demographic data will be collected from every record audited. Demographic data audit to include:

- Trauma identification number
- Date of birth
- Gender
- Race
- Resident zip
- Injury date
- Place of injury
- Admit date
- Discharge date

The Trauma Program Manager can select **additional** sections or identify specific data points in the data dictionary agreed upon by the COTS staff relevant to their specific Performance Improvement.

If there is no specific request the TPM and COTS staff will select 2 of the following data sections for review:

Section 1: Outcome data to include:

- Pre-existing conditions (co-morbidities)
- Discharge status
- Autopsy performed
- Complications

Section 2: Anatomic diagnosis data to include:

- Diagnosis International Classification of Disease; Tenth Edition (ICD-10) code
- AIS code
- AIS body region
- Calculated ISS

Section 3: Operating Room procedure data to include (when procedures location is the OR):

- Procedure ICD-10 code
- Procedure start date
- Procedure start time
- Procedures listed from Appendix A***** that would have been performed in the OR

Section 4: Other procedure data performed outside the OR to include:

- Procedure location
- Procedure ICD-10 code for all procedures listed from Appendix A***** that would have been performed in the Emergency Department (ED), ICU, Floor, Radiology, and other

*****Ohio Trauma Registry (OTR) Data Dictionary 2020 page 103.

The number and category of records to be audited will be sent to the Trauma Center approximately 2 weeks prior to the visit.

<u>EVALUATION</u>:

Audited data will be compared against the Trauma Center's download to the COTS Trauma Registry. The audit inclusion dates will be determined by the most recent data download to COTS.

<u>REPORT</u>:

A report will be sent to the Trauma Program Manager within 30 days identifying areas of compliance versus data incongruence. The Trauma Program Manager can request additional information, as needed, to analyze results. The acceptable range of error is determined by each institution and manager.

APPENDIX A

PROCEDURE LIST FOR *HOSPITAL PROCEDURES* ELEMENT

DIAGNOSTIC & THERAPEUTIC IMAGING
Computerized tomographic studies* (Head, Chest, Abdomen, Pelvis, C-Spine, T-Spine, L-Spine)
Diagnostic ultrasound (includes FAST)*
Doppler ultrasound of extremities*
Angiography
Angioembolization
REBOA
Inferior vena cava (IVC) filter

CARDIOVASCULAR
Open cardiac massage
Cardiopulmonary Resuscitation (CPR)

CENTRAL NERVOUS SYSTEM
Insertion of ICP monitor*
Ventriculostomy*
Cerebral oxygen monitoring*

GASTROINTESTINAL
Endoscopy (includes gastroscopy, sigmoidoscopy, colonoscopy)
Gastrostomy/jejunostomy (percutaneous/or endoscopic)
Percutaneous (endoscopic) gastrojejunoscopy

GENITOURINARY
Ureteric catheterization (i.e. ureteric stent)
Suprapubic cystostomy

MUSCULOSKELETAL
Soft tissue/bony debridement*
Closed reduction fractures
Skeletal (and halo) traction
Fasciotomy

RESPIRATORY
Insertion of endotracheal tube* (Exclude intubations performed in the OR)
Continuous invasive mechanical ventilation*
Chest tube*
Bronchoscopy*
Tracheostomy

TRANSFUSION
The following blood products should be captured over first 24 hours after hospital arrival:
Transfusion of red cells *
Transfusion of platelets *
Transfusion of plasma *

REFERENCES:

1. *Mississippi Bureau of Acute Care Systems Trauma Programmatic Audit and Financial Review Manual Level I, II, and III Trauma Centers; Pediatric Centers; Burn Centers; and EMS Providers As of June 2015: A sampling of no less than 10% of the total Trauma Registry records for the fiscal year will be reviewed, with an error rate not to exceed 2%.
2. *Audit command language (ACL) software programs: ACL software performs the same calculation as an attribute-sampling table utilizing the table below:

Expected Error Rate	Tolerable Error			
	2%	3%	4%	5%
0.00%	124	78	66	58
1.00	153	103	88	77
2.00	181	127	103	81
3.00	208	150	109	91

3. *Determining Sample Size Tool: http://www.surveysystem.com/sscalc.htm

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Records to be pulled for a random chart audit

Completed by COTS: Sent to Trauma Program Manager 2 Weeks Prior Identifying the Number of Records to be pulled for Primary External Validation Audit

Date(s) Primary External Validation Audit will be conducted:

External Audit Inclusion Dates:

Records to be pulled for Primary External Validation Audit by Category:

The hospital will identify the records within each category they want to submit for Primary External Validation Audit. Please provide a complete list of these records including trauma base number and discharge date. Do not use patient identifier when generating this list.